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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,170	09/23/2003	Bruce H. KenKnight	279.565USI	1699

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EXAMINER	
REIDEL, JESSICA L	

ART UNIT	PAPER NUMBER
3766	

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06/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/669,170	KENKNIGHT ET AL.	
	Examiner	Art Unit	
	Jessica L. Reidel	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11,12 and 14-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11,12 and 14-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 2, 2007 has been entered. Claims 1-11 and 13 are cancelled. Claims 11-12 and 14-20 are pending.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on June 4, 2007 has been acknowledged and is being considered by the Examiner.

Oath/Declaration

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application, by application number and filing date, is required. See MPEP §§ 602.01 and 602.02.

> The oath or declaration is defective because:
> It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56.

Specifically, the oath/declarations do not have the correct statement with respect to the duty to disclose. This applies to all applications, not just reissue applications.

A CORRECT STATEMENT should read, "I acknowledge the duty to disclose information which is material to patentability of this application in accordance with Title 37, Code of Federal Regulations Section 1.56."

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. ***Claims 11-12 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kramer et al. (U.S. 2002/0161410) (herein Kramer '410) in view of Ding (U.S. 6,424,865) (herein Ding).*** As to Claims 11 and 19-20, Kramer '410 expressly discloses a method for treating congestive heart failure comprising implanting a cardiac pacing device, having a plurality of pacing channels, in a patient so as to allow paces to be delivered to a plurality of ventricular sites (see Kramer '410 Abstract, Fig. 1 and pages 3-4, paragraphs 18-21). Kramer '410 also expressly discloses that the implantable cardiac pacing device is configured to deliver cardiac function therapy that effects reversal of ventricular remodeling by delivering pacing pulses to one or more stressed and/or hypertrophied ventricular regions in a manner that pre-excites those regions relative to other ventricular regions (see Kramer '410 Figs. 2A-2B, pages 1-

2, paragraphs 3-8, page 3, paragraph 17 and page 4-5, paragraphs 27-29). Kramer '410 specifies that in one embodiment the implantable cardiac pacing device may be configured such that "a pre-excitation stimulation pulse is applied to a stressed region either alone or in a timed relation to the delivery of a stimulation pulse applied elsewhere to the myocardium" and in other embodiments the implantable cardiac pacing device may be configured such that multiple electrodes and stimulation channels deliver pulses to multiple pacing sites "in accordance with a specified pulse output sequence". In any of the embodiments disclosed by Kramer '410, the principal remains the same: unloading a stressed myocardial site by pre-exciting it relative to other regions of the myocardium (see Kramer '410 pages 3-4, paragraph 21).

The method of Kramer '410 further comprises configuring the implantable cardiac pacing device to assess the patient's cardiac function by measuring a physiological variable affected by reversal of remodeling, such that the specified pulse output sequence of the cardiac function therapy may be adjusted in accordance with measurements of the physiological variable. The physiological variable measured may include conduction delays of excitation spreading through the myocardium, where increased conduction delays indicate worsening ventricular remodeling through a region of myocardial tissue. Kramer '410 teaches that the pre-excitation interval of the cardiac function therapy may be adjusted in accordance with detected changes in the remodeling process and further that the interval may be shortened as remodeling is reversed or increased as remodeling worsens. The adjustment of the cardiac function therapy delivered by the implantable cardiac pacing device of Kramer '410 is configured such that it continues delivery of the cardiac function therapy, in an adjusted mode, based on the cardiac function assessment (see Kramer '410 page 4, paragraph 27).

Kramer '410 discloses the claimed invention as previously discussed except that it is not specified that that the implantable cardiac pacing device temporarily suspend the pre-excitation treatment such that assessment of cardiac function takes place while no cardiac function therapy is being delivered. The Examiner, however, considers it to be conventional and well known in the art of implantable cardiac therapy devices for changes in a patient's conduction system to be assessed while no therapy is being delivered to the heart such that the conduction pathway assessment is reflective of the heart's intrinsic conduction patterns and provides Ding as being but one example. Ding discloses a method of monitoring changes in ventricular activation patterns in order to detect changes in the heart's intrinsic conduction system that may occur due to physiological remodeling of the heart (see Ding column 2, lines 25-60). Ding specifies that either after turning pacing off (via command from an external programmer) or during a heartbeat in which no ventricular pacing is delivered (periodically), ventricular depolarizations are detected in order to calculate conduction delays that may exist between at least two ventricular sites. The intrinsic conduction delays are an accurate reflection of improving or worsening heart failure and can be used by an implantable cardiac pacing device of Ding in order to optimally adjust pacing parameters (see Ding Figs. 2-3, column 3, lines 5-43, column 4, lines 54-67 and column 5). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Kramer '410 to include temporarily suspending the cardiac function therapy such that assessment of cardiac function, specifically the assessment of changes that may occur in the patient's conduction system by measuring conduction delays, take place while no cardiac function therapy is being delivered as taught by Ding since such a

modification would allow for accurate intrinsic assessment of improving or worsening heart failure useful for optimal adjustment of the cardiac function therapy.

7. As to Claim 12, Kramer '410 expressly discloses that the cardiac function therapy may include both the pre-excitation type for reversal of remodeling when the patient's metabolic demands are low and one that is designed to produce hemodynamically more effective contractions when the patient's metabolic demands are high, both of which improves the patient's cardiac pumping performance (see Kramer '410 pages 1-2, paragraph 8). Reversing ventricular remodeling with the pre-excitation inherently improves the cardiac pumping performance of the heart since pre-exciting stressed regions allows those regions to experience less after-load and pre-load, effectively changing the wall stresses developed near those regions during systolic contraction (see Kramer '410 page 3, paragraphs 16 and 21).

8. ***Claims 14 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kramer '410 in view of Ding as applied to claim 11 above, and further in view of Salo et al. (U.S. 5,487,752) (herein Salo)***. As to Claim 14, the previously modified Kramer '410 reference discloses the claimed invention as previously discussed except it is not specified that the method include measuring cardiac output and comparing the measured cardiac output to a specified threshold value.

Salo, however, teaches that it is well known in the art of stimulation devices to optimize pacing parameters for treating congestive heart failure by measuring cardiac output for a plurality of pacing therapies having different parameters and selecting the optimal pacing therapy by selecting the therapy which yields the maximum cardiac output, where the measured cardiac outputs are compared to a baseline cardiac output, read as a specified threshold value (see Salo

Fig. 5 and columns 5-6). Salo measures cardiac output using known impedance plethysmography techniques to measure stroke volume, where measured cardiac output is calculated by multiplying measured stroke volume by a measured heart-rate (see Salo column 4, lines 37-41) or by other well known-techniques either invasive or non-invasive (see Salo). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Kramer '410 in view of Ding and Salo to include measuring cardiac output for a plurality of pacing therapies having different parameters and comparing the measured cardiac outputs to a specified threshold value such that the pacing therapy that produces the maximum cardiac output may be implemented to effectively treat a congestive heart failure.

9. As to Claim 16, Kramer '410 expressly discloses that the cardiac function therapy may include both the pre-excitation type for reversal of remodeling when the patient's metabolic demands are low and one that is designed to produce hemodynamically more effective contractions when the patient's metabolic demands are high (see Kramer '410 pages 1-2, paragraph 8). The sequence of the cardiac function therapy (i.e. whether to deliver pre-excitation reverse remodeling therapy or whether to deliver therapy that promotes effective contractions) is adjusted automatically in accordance with an exertion level measured by exertion level sensor 52 (see Kramer '410 Fig. 1, page 3, paragraphs 18-19 and page 4, paragraph 28).

10. ***Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kramer '410 in view of Ding and Salo as applied to claim 14 above, and further in view of Burnes (U.S. 2004/0220636) (herein Burnes).*** The previously modified Kramer '410 reference discloses the claimed invention as previously discussed except it is not specified that the cardiac output be measured by measuring tans-thoracic impedance. The Examiner considers it conventional and

well known in the art to use measured trans-thoracic impedance for assessing cardiac output and cites Burnes as being but one example. Burnes teaches that it is well known in the art of implantable medical devices, such as cardiac resynchronization devices, to improve selection of pacing parameters by measuring trans-thoracic impedance such that the selection of pacing parameters optimizes hemodynamic function (see Burnes page 1, paragraphs 5-8, page 3, paragraphs 27-29, page 4, paragraphs 36-37, page 6, paragraph 62 and page 7).

11. ***Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kramer '410 in view of Ding as applied to claim 11 above, and further in view of Struble et al. (U.S. 2003/0199956) (herein Struble).*** As to Claim 14, the previously modified Kramer '410 reference discloses the claimed invention as previously discussed except it is not specified that the method include measuring cardiac output and comparing the measured cardiac output to a specified threshold value.

Stuble, however, teaches that when employing a multi-chamber pacing modality, such as bi-ventricular or multi-site pacing, in an effort to produce hemodynamically more effective contractions it is well known in the art to measure cardiac output (using oxygen saturation sensing) and compare that measurement to a specified threshold value (316). Struble teaches that this measurement and comparison is technique ensures that the cardiac rhythm managment is in face producing hemodynamically more effective contractions and if it is not (i.e. cardiac output is measured to be below the specific threshold value) it is preferable to modify the pacing modality to produce hemodynamically more effective contractions (see Struble Fig. 13, Abstract, page 2, paragraphs 13-17 and page 11, paragraphs 109-111). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of

Kramer '410 in view of Ding and Struble to include assessing the patient's cardiac output by measuring a physiological variable of cardiac output and comparing it to a specified threshold value, such that cardiac rhythm management may be optimized to produce hemodynamically more effective contractions.

12. As to Claim 15, Stuble does not expressly disclose that the cardiac output is measured by measuring a trans-thoracic impedance and heart rate. Instead, as previously discussed, Struble uses oxygen saturation in order to measure cardiac output.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art at the time the invention was made to measure cardiac output in a patient by measuring trans-thoracic impedance and heart rate because Applicant has not disclosed that by measuring trans-thoracic impedance and heart rate in order to measure cardiac output provides an advantage, is used for a particular purpose, or solves a stated problem. One or ordinary skill in the art, furthermore, would have expected Struble's measurements of oxygen saturation, and Applicant's invention, to perform equally well with either the oxygen saturation measurements taught by Struble or the claimed trans-thoracic impedance and heart rate measurements because both perform the same function of measuring cardiac output equally well.

Therefore, it would have been prima facie obvious to modify Kramer '410 in view of Ding and Struble to obtain the invention as specified in Claim 15 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art.

13. As to Claim 16, Kramer '410 expressly discloses that the cardiac function therapy may include both the pre-excitation type for reversal of remodeling when the patient's metabolic demands are low and one that is designed to produce hemodynamically more effective contractions when the patient's metabolic demands are high (see Kramer '410 pages 1-2, paragraph 8). The sequent of the cardiac function therapy (i.e. whether to deliver pre-excitation reverse remodeling therapy or whether to deliver therapy that promotes effective contractions) is adjusted automatically in accordance with an exertion level measured by exertion level sensor 52 (see Kramer '410 Fig. 1, page 3, paragraphs 18-19 and page 4, paragraph 28).

14. ***Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kramer '410 in view of Ding as applied to claim 11 above, and further in view of Zhu et al. (U.S. 2002/0120306) (herein Zhu).*** The previously modified Kramer '410 reference discloses the claimed invention as previously discussed except it is not specified that the method include assessment of the patient's autonomic balance by measuring the patient's heart rate variability using a spectral analysis where a LF/HF ratio is compared to a specified threshold.

Zhu, however, teaches that because implantable cardiac rhythm management devices have limited processing power and are powered by a battery, replacement of which requires re-implantation, it is not practical for a device to continuously perform the computationally intensive data analysis, often necessary in order for the device to detect arrhythmias such as tachycardia and/or fibrillation (see Zhu page 1, paragraphs 3-5). Zhu teaches that it is beneficial for most implantable cardiac rhythm management devices, including cardiac resynchronization devices, to implement heart rate variability assessments, using a spectral analysis where a LF/HF ratio is compared to a specified threshold, in order to trigger intensive data analysis needed for

arrhythmia detection (see Zhu pages 1-3, paragraphs 12-21 and pages 4-5, paragraphs 35-41). It would have been obvious to one having ordinary skill in the art to modify the method of Kramer '410 in view of Ding and Zhu to include measuring the patient's heart rate variability using a spectral analysis where a LF/HF ratio is compared to a specified threshold since such a modification would allow the device to effectively operate, while conserving processing power, and having the ability to enter a diagnostic mode for arrhythmia detection.

15. ***Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kramer '410 in view of Ding as applied to claim 11 above, and further in view of Pastore et al. (U.S. 7,065,405) (herein Pastore).*** The applied reference has a common Assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The previously modified Kramer '410 reference discloses the claimed invention as previously discussed except it is not specified that the method include assessment of the patient's autonomic balance by measuring the patient's heart rate variability using a spectral analysis where a LF/HF ratio is compared to a specified threshold. Pastore, however, teaches that it is well known in the art of cardiac rhythm management to deliver synchronous pacing/resynchronization pacing and to only to enter into a stress reduction mode (i.e. cardiac function therapy that effects reversal of ventricular remodeling by delivering pacing pulses to one or more stressed and/or hypertrophied ventricular regions in a manner that pre-excites those regions relative to other ventricular regions) when a pre-arrhythmic condition is detected (see Pastore column 2, lines 5-31, column 3, lines 44-67, column 4, lines 1-23 and column 10, lines 46-54). Pastore specifies that a pre-arrhythmic condition is detected by assessing autonomic function of the patient using a spectral analysis of the heart rate variability and comparing LF/HF to a threshold. Pastore teaches that this allows the cardiac rhythm management delivered by an implantable medical device to both increase hemodynamic performance and to prevent arrhythmias (see Pastore columns 3-4, column 7, lines 49-67 and column 8, lines 1-34). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Kramer '410 in view of Ding and Pastore to include assessment of the patient's autonomic balance by measuring the patient's heart rate variability using a spectral analysis where a LF/HF ratio is compared to a specified threshold such that a stress reduction mode is only applied when a pre-arrhythmic condition is detected in order to apply a cardiac rhythm management to a flailing heart that both improves hemodynamic performance and prevents arrhythmias.

Response to Arguments

16. Applicant's arguments with respect to claims 11-12 and 14-20 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure.

Girouard et al. (U.S. 7,158,824) (herein Girouard) teaches that it is known in the art for an implantable cardiac rhythm management device to switch between two different pacing modalities (i.e. stress reduction pacing for stabilization of arterial plaque as one modality and resynchronization or reversal of remodeling as other modalities) in accordance with a measured physiological variable such as exertion level or heart rate.

Kramer et al. (U.S. 7,103,410) (herein Kramer et al.) disclose methods for treating congestive heart failure, synonymous to that of Kramer '410, discussed above in this Office Action.

Kroll et al. (U.S. 6,748,261) (herein Kroll) teaches that relative changes in the interchamber intrinsic conduction delays, over time, are indicative of progression or regression in heart disease and these changes may be used to automatically adjust pacing parameters.

Park et al. (U.S. 6,456,880) (herein Park) teaches that when monitoring the progression or regression of a patient's heart condition, a more accurate determination is made when the measurements of cardiac function are made when the patient is at rest or when heart rate and activity levels are below predetermined limits.

van Dam et al. (U.S. 2004/0215238) (herein van Dam) teaches that when measuring a physiological variable in order to assess myocardial wall thickness it is important to ensure that the measurement is taken under stable conditions else the physiological measurement may not be a true or accurate depiction of wall hypertrophy and congestive heart failure.

18. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The Examiner can normally be reached on Mon-Thurs 8:00-5:30, every other Fri 8:00-4:30.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Angela D. Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jessica L. Reidel/
Patent Examiner, Art Unit 3766
June 20, 2007

/Kennedy J. Schaetzle/
Primary Examiner, AU 3766
June 22, 2007